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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,657	02/03/2004	John Nelson	PB0308	4149

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GE HEALTHCARE BIO-SCIENCES CORP.
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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/770,657

Applicant(s)

NELSON, JOHN

Examiner

Kenneth R. Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 25 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/8/06</u> | 6) <input type="checkbox"/> Other: _____ |

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-22, 25, and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Kumar et al. (US 6,977,153, filed 12/31/02).

Claims 1-5 are drawn to methods comprising reverse transcribing RNA to form cDNA; self-ligating the cDNA to form circular products; and amplifying the ligated cDNA products by rolling circle amplification using random-sequence primers and DNA polymerase. Claims 6-13 are similar, further including use of a primer comprising an RNA polymerase promoter and the step of transcribing amplified DNA using RNA polymerase. Claims 14-21 are similar, but wherein amplification is via one or more specific primers in isothermal amplification. Claims 22, 25, and 28 relate to conventional uses of such methods, and claims 29-30 are drawn to kits suitable for use in such methods.

Kumar et al. disclose such methods; further applications for such methods, and kits; see entire document, especially Fig. 1 and columns 2-5, 19-20, and 53.

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3. The declaration filed on 11/21/06 under 37 CFR 1.131 has been considered but is ineffective to overcome the Kumar et al. reference.

The Kumar et al. reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION BASED ON ART NEWLY
DISCLOSED BY APPLICANT IN THE IDS FILED 09/08/06**

4. Claims 1-5 and 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Beach et al. (US 2003/0082559, filed 01/22/02).

Beach et al. disclose the claimed methods, see paragraphs 0042-0046, 0055, and 0450-0481.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-13, 22, 25, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beach et al. in view of Cleuziat et al.

Beach et al. do not disclose the use of primers comprising RNA promoter sequences and transcribing amplified DNA using RNA polymerase, nor the exact kits of the claims, which require RNA polymerase.

Cleuziat et al. disclose the use of primers comprising RNA promoter sequences and transcribing amplified DNA using RNA polymerase (see Fig. 2 and column 7, lines 18-45).

One of ordinary skill in the art would have been motivated to modify the method of Beach et al. by using primers comprising promoter sequences because Cleuziat et al. taught that such primers advantageously facilitate the production of RNA using RNA polymerase from amplification products. The skilled artisan would have been motivated to make the claimed kits, comprising reverse transcriptase, ligase, phi29 DNA polymerase, RNA polymerase, and nuclease resistant primers, because such kits would have been useful in carrying out the method as suggested by these combined references. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods, and to make and use the claimed kits.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY THE
AMENDMENT**

6. Claims 1-5 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (US 5,876,932) in view of Lizardi (US 5,854,033).

Fischer discloses the claimed methods, except for the use of rolling circle amplification to amplify circular product; see entire document, especially column 3, lines 25-39; column 5, lines 14-43; column 9, lines 4-37; and paragraph bridging columns 11 and 12.

Lizardi discloses rolling circle amplification as an advantageous means of amplifying circular nucleic acids (see Fig. 3 and columns 2-35).

One of ordinary skill in the art would have been motivated to use rolling circle amplification in the method of Fischer because Lizardi disclosed this advantageous means of amplifying circular nucleic acids. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

7. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connor et al. (US 2002/0004592) in view of Lizardi (US 5,854,033).

Connor et al. disclose the claimed methods, except for the use of rolling circle amplification to amplify circular product; see entire document, especially Fig. 1 and paragraphs 0014, 0018, and 0031-0094.

Lizardi discloses rolling circle amplification as an advantageous means of amplifying circular nucleic acids (see Fig. 3 and columns 2-35).

One of ordinary skill in the art would have been motivated to use rolling circle amplification in the method of Connor et al. because Lizardi disclosed this advantageous means of amplifying circular nucleic acids. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

8. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al. (US 2002/0164629, effective filing date 03/12/01) in view of Lizardi (US 5,854,033).

These claims are drawn to a kit comprising: reverse transcriptase, ligase, phi29 DNA polymerase, RNA polymerase, and nuclease resistant primers; and to such a kit wherein said primers are random sequence primers.

Quake et al. disclose methods utilizing these four enzymes, as well as random primers (see paragraphs 0052, 0066 and 0101-0102).

Quake et al. do not disclose nuclease resistant primers, nor kits in general.

Lizardi discloses nuclease resistant primers (column 10, lines 25-33), as well as the concept of kits (column 19, lines 17-19).

One of ordinary skill in the art would have been motivated to make a kit comprising the recited components because it would have clearly been useful in the practice of the methods of Quake et al., which utilize said components. The skilled

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artisan would have been motivated to modify such a kit to contain primers which were nuclease resistant because the benefits of nuclease resistant primers were taught by Lizardi. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

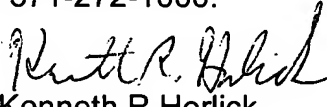
9. No claims are free of the prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 Ph.D.
Kenneth R Horlick
Primary Examiner
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02/06/07